1	2	3	4	5	6	7	8	9	10	11	12
Kerala	0	1	0	0	0	0	0	0	0		
Daman & Diu	0	0	0	0	0	0	0	0	0		
D & N Haveli	0	0	0	0	0	0	0	0	0		
Goa	0	0	0	0	0	0	0	0	0		
Pondicherry	0	0	0	0	0	0	0	0	0		
Andaman & Nicobar	0	0	0	0	0	0	0	0	0		
Arunachal Pradesh	0	0	0	0	0	0	0	0	0		
Lakshadweep	0	0	0	0	0	0	0	0	0		
Manipur	0	0	0	0	0	0	0	0	0		
Meghalaya	0	0	0	0	0	0	0	0	0		
Mizoram	0	0	0	0	0	0	0	0	0		
Nagaland	0	0	0	0	0	0	0	0	0		
Sikkim	0	0	0	0	0	0	0	0	0		
Tripura	0	0	0	0	0	0	0	0	0		
TOTAL	1126	265	268	1600	225	134	66	676	874	559	10

Compensation to victims of clinical trials

647. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether in view of growing number of clinical researches in the country and also in view of India becoming popular destination for clinical research, Government plans to formulate guidelines or code on clinical research with emphasis on giving compensation to participants who suffer economical, social, psychological and physical damages; and

(b) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Guidelines and requirements for conducting clinical trial in the country are specified in the Schedule Y of Drugs and Cosmetic Rules.

Clinical Trial in country is required to be conducted as per Schedule Y, which also mandates conformance to Indian Good Clinical Practices (GCP) Guidelines. The Para 2.4.7 of Indian GCP guidelines prescribes provision for compensation to trial subject by sponsor in case of any harm caused to them during the trials.

In order to ensure that Clinical trials are conducted in the country as per regulation & Good Clinical Practice (GCP) guidelines, it has been felt necessary to register the Organizations conducting clinical trial. Draft guidelines for the same have been prepared, which would be placed before forthcoming Drugs Technical Advisory Board Meeting to be held on 23.02.2009.